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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,311	01/11/2006	Hidehito Kotani	BY0027P	7112
210	7590	01/03/2008		
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			EXAMINER ZARA, JANE J	
			ART UNIT	PAPER NUMBER
			1635	
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			01/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,311

Applicant(s)

KOTANI ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-26-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 10-29-07.

Claims 1 and 22-24 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group III, claim 1, in the reply filed on 10-29-07 is acknowledged. The traversal is on the ground(s) that rewritten Claim 1, now new Claim 23, be examined simultaneously because a search of one Group (Group III) will include a search of the other Group (Group IV), and because both Group III and IV are drawn to methods of measuring a compound's affect on LCE activity, Group IV merely includes measuring the affect of a compound on LCE protein activity in the presence of other elongases.

Claims 1, 22-24 have been examined on their merits as set forth in the Office action below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 does not further limit claim 23, from which it depends. Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Berghs et al (WO 2004/013347).

Berghs et al (WO 2004/013347) teach methods of evaluating compounds that are effective for treating obesity comprising contacting an LCE protein with a test compound, as well as contacting LCE with a test compound in the presence of a plurality of elongase proteins, and selecting the test compounds that inhibit LCE activity (see the abstract, pages 5-9, 14, 17-18, and claims 1, 2, 6, 11-13, 17-19, 24, 25 and 28; SEQ ID No. 17, encoding SEQ ID No. 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moon et al (J. Biol. Chem., Vol. 276, No. 48, pages 45,358-45,366, 2001) in view of Matsuzaka et al (J. Lipid Res., Vol. 43, pages 911-920, 2002).

The claims are drawn to methods of evaluating compounds that are effective for treating obesity comprising contacting an LCE protein with a test compound, as well as contacting LCE with a test compound in the presence of a plurality of elongase proteins, and selecting the test compounds that inhibit LCE activity.

Moon et al (J. Biol. Chem., Vol. 276, No. 48, pages 45,358-45,366, 2001) teach the cloning and expression of LCE, its increased expression in liver and adipose tissue, its potential role in obesity, and assaying LCE activity in presence of other elongases, as well as in the presence and absence of cofactors (e.g. NADPH) and at varying pH (see esp. the text on p. 45,358; the Methods Section entitled "In Vitro Fatty Acid Elongation Assay" on pages 45,359-45,360; Figure 3 on page 45,361; text on page 45,362; figure 6 and text on page 45,363; text on page 45,364; figure 9 and text on page 45,365).

Moon does not identify compounds that inhibit LCE enzymatic activity.

Matsuzaka et al (J. Lipid Res., Vol. 43, pages 911-920, 2002) teach the cloning and characterization of LCE, its role among other elongase enzymes in the lipogenic process, its increased expression in obesity models, the identification of various agonists of LCE expression, the enzyme's (post-transcriptional and transcriptional) response to stimuli such as nutrient intake and hormones, and LCE's potentially

required role in human obesity (see esp. the abstract on p. 911; left column on page 912; text on pages 915-916; text on page 917-919).

It would have been obvious to one of ordinary skill in the art to screen for inhibitors of LCE enzymatic activity because the enzyme had been cloned, recombinantly expressed, and an activity assay developed by both Moon and Matsuzaka. One of ordinary skill would have been motivated to screen for inhibitors of LCE enzyme activity because elevated levels of LCE activity had been associated with obesity, and it had been identified as a lipogenic protein, therefore screening for inhibitors of LCE activity would have provided likely candidates for inhibiting the elongase activity, thereby inhibiting the increase in fatty compositions of liver, and potentially inhibiting lipogenic enzyme activity that is required in the obese state. One of ordinary skill in the art would have had a reasonable expectation of success in identifying candidate inhibitors of LCE activity by utilizing the routine assay protocols set forth by both Moon and Matsuzaka and comparing the LCE activity in the absence and presence of candidate compounds, and since this enzyme was known to increase fatty compositions in the liver, one would have a reasonable expectation that finding an inhibitor of LCE activity would also provide a potential candidate for inhibiting obesity in vivo. One of ordinary skill would have been motivated to screen for candidate inhibitors of LCE activity because this enzyme was known in the art to be more highly expressed in an obese state, it had been recombinantly expressed, and assaying its activity in the presence and absence of candidate inhibitors would have required routine experimentation at the time the invention was made. One of ordinary skill in the art

would have been motivated to screen for inhibitors of enzyme activity, in addition to screening for inhibitors of enzyme expression, because enzyme inhibitors would provide an alternative route of fatty acid synthesis regulation for treatment approaches, and would provide the potential for more finely tuned or short term inhibition of LCE activity compared to inhibitors of enzyme expression.

For these reasons, the instant invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of

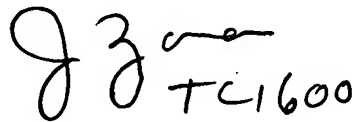
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a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
12-27-07

Handwritten signature of Jane Zara, with the text "TC1600" written below it.

JANE ZARA, PH.D.
PRIMARY EXAMINER